



< xmLabeling® />

SPL OTC Sub-Team Vendor Webinar

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Webinar Agenda

- Introduction to Glemser Technologies
- SPL R4 Overview
- Introduction to xmLabeling
- xmLabeling Demonstration
- Questions and Answers



Introduction to Glemser Technologies

Tamara Healy, Business Development Manager



Partner for This Solution – Glemser Technologies

- Glemser was incorporated in 1987 and has been implementing global labeling solutions for large pharmaceutical companies since 2001 and is recognized as an industry leader with specialized domain experience and technical expertise in SPL and PIM
- Glemser is a member of the FDA's SPL Working Group and is recognized as a key contributor to the emerging standards
- Glemser has been a Documentum partner for 10 years and focuses on designing, implementing, and validating XML and content management solutions for life sciences companies
- Glemser has significant experience in implementing global Documentum-based solutions for large companies such as Pfizer, J&J and GSK
- Glemser is headquartered in Bethlehem, PA and has offices in New Jersey, Massachusetts and India





We are Focused Exclusively on Life Sciences

Our exclusive focus on life sciences gives us unmatched experience, expertise and insight into the underlying business processes involved in managing product labeling content



- We focus exclusively on providing regulatory compliance solutions to life sciences firms
- Content management solutions comprise virtually 100% of our business
- About 80% of the solutions we implement are Documentum-based
- We have an emerging SharePoint practice



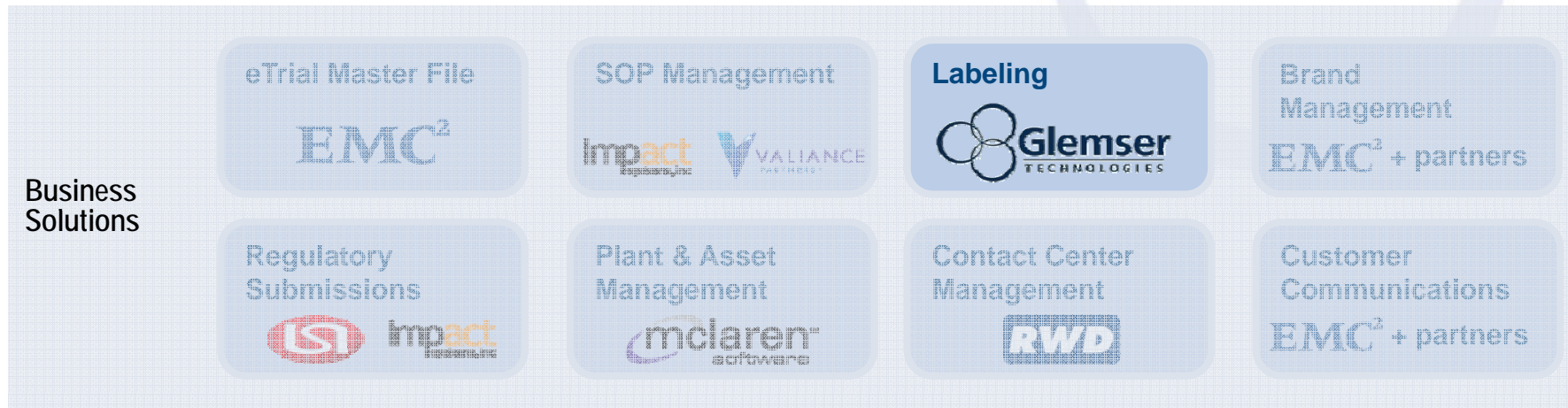
Glemser is a Leader in Pharmaceutical Labeling

Glemser has developed deep global pharmaceutical labeling experience while implementing solutions for over 7 years

- We built a custom global labeling solution for a global pharmaceutical company in 2001- 2002
 - Deployed to ~ 120 countries
 - Upgraded to support storage of SPL labeling for US package inserts
- We developed and continue to enhance an off-the-shelf labeling product called xmLabeling
 - SPL & PIM systems are implemented in production at several large pharmaceutical companies
 - Continue to support emerging US and EU standards (such as PIM DES 2.6.1 and SPL 4.0)
- We are actively involved in industry organizations supporting SPL and PIM
 - Work closely with EU clients in supporting PIM standards development
 - Participate in SPL working groups in the US
 - Present as SMEs in related industry events
- We have substantial experience in XML conversion and submission processes through our SPL on Demand conversion services for a number of pharmaceutical companies



Glemser is EMC's Partner for Labeling



- EMC has chosen Glemser as its strategic partner for labeling within its life sciences solution suite
- xmLabeling has earned the Designed for EMC certification. This means that these solutions have been verified as architected to ensure compliance with EMC Documentum's technical strategy.
- Glemser's xmLabeling solution was selected as the winner of the "Best Platform Utilization" award by EMC in 2007





SPL R4 Overview

Tammy Feichtel, xmLabeling Product Manager



SPL R4 - Overview

- Changes in FD&C Act require electronic registration of all drug establishments and listing for human prescription drugs, OTC, animal drug, and biologic products
- Since 2005 FDA has adopted the HL7 approved document markup standard of SPL for exchanging medication information for Content of Labeling. Now with SPL R4, FDA has expanded their systems to also process establishment registration, NDC label code requests and enhanced drug listing in SPL format.
- With the implementation of SPL R4, the FDA intends to only accept electronic drug establishment registration and drug listing information beginning June 1, 2009 (unless a waiver is granted)
- Electronic submission of these forms would lead to significant improvements in the timelines and accuracy of the information received compared with the current paper-based system



SPL R4 - Replacement of Paper Forms

SPL R4 revises the current regulations to require that Registrants and Private Label Distributors replace paper forms with SPL files for electronic submission

- The following paper forms are being replaced with electronic submissions in SPL format:
 - FDA - 2656 – Registration or Drug Establishment/Labeler Code Assignment
 - FDA - 2657 – Drug Listing
 - FDA - 2658 – Registered Establishments' Report of Private Label Distributors



SPL R4 - Changes to Requirements & Schema 1 of 3

- Change location of schema and style sheet from the Data Council web server to the Access Data web server
 - Style sheet and schema location is referenced in the SPL processing information at the top of the XML file
- FDA will no longer make changes to SPL (e.g. version, effective time)
 - Applicants will now manage submission versions and effective times
 - If any changes are required, applicants will be notified by the Agency and applicants will make changes to their submissions and re-submit
- Change GUIDS from uppercase to lowercase for all types of SPL submissions
- Change specifications for SPL title and Highlights “boilerplate”
 - FDA is now requiring applicants to include previously generated boilerplate text in their PLR submissions
 - FDA is allowing applicants to add a title element to SPL with and without Highlights (previously this was only generated by FDA style sheets)



SPL R4 - Changes to Requirements & Schema 2 of 3

- Replace <manufacturedMedicine> elements with <manufacturedProduct> elements
- Replace <activeIngredient> and <inactiveIngredient> elements with <ingredient> element
 - Add the class code attribute to the <ingredient> element to designate basis of strength with the following values
 - INGR – for ingredients included in devices**
 - ACTIB – if basis of strength is the active ingredient
 - ACTIR – if the basis of strength is a reference drug
 - ACTIM – if the basis of strength is the active moiety
 - IACT – for inactive ingredients

*** Functionality added as defined in FDA implementation guide anticipating future requirements of SPL submissions for Devices*



SPL R4 - Changes to Requirements & Schema 3 of 3

- Delete <translation> element for strength units of measure
 - <translation> element will only be used for packaging if the Unified Codes for Units of Measure (UCUM) code is “1”
- NOTE: UCUM codes are defined on the FDA website*
- Change unit of measure for patch dosage forms from “each” to “time”
- Remove drug product characteristics for “symbol” and “coating”



SPL R4 - Additional Listing Information 1 of 2

- Addition of new Product characteristics
 - SPLFLAVOR
 - SPLCONTAINS
- Addition of Suffix for proprietary name
 - Used for descriptors, such as “extended release”
- Addition of <confidentialityCode>
 - Element uses attribute code=“B” for business confidential information
 - Allowed for Inactive ingredients, registrant and establishment information in the SPL Content of Labeling and Listing submission
 - Information within this element is redacted by the Agency before posting to the Daily Med
- Addition of <InstanceOfKind> element to describe devices’ model number, serial number, and lot number**

*** Functionality added as defined in FDA implementation guide anticipating future requirements of SPL submissions for Devices*



SPL R4 - Additional Listing Information 2 of 2

- Addition of elements to capture the following Marketing Category and Status Information for each Drug Product
 - Application Number
 - Marketing Category
 - e.g. NDA, ANDA, OTC monograph final, etc...
 - Marketing Status
 - e.g. Active (still on the market), completed (no longer on the market)
 - Approval Year (time product on and off the market)
 - Stored in <effective_time> element now child of <marketingAct> [previously stored in <time> element in SPL header]
 - Agency will use this effective time value to determine when to remove labels off the Daily Med
- Addition of an SPL Image associated with each Drug Product
 - This image is an actual representation of the associated solid/oral dosage form product
 - Used to reduce counterfeit and prescription errors



Introduction to <xmLabeling®/>

Andy Glemser, Vice President Marketing



xmLabeling Overview 1 of 2

- xmLabeling is Glemser's comprehensive, configurable, off-the-shelf solution for the management of pharmaceutical labeling content
- xmLabeling is a fully integrated structured content management system, not just an SPL editor
- xmLabeling supports agency-specific XML submission requirements:
 - SPL R4 format for US submissions
 - ◆ Listing, NDC Labeler Code Requests, and Establishment Registrations
 - Product Information Management (PIM) format for EU centralized registrations
- xmLabeling provides full lifecycle support for all global product information, including:
 - Core data sheets and related compliance tracking
 - National product information in MS Word and PDF formats

<xmLabeling®/>



xmLabeling Overview 2 of 2

- Leveraging OTB functionality, best practice configurations, and implementation accelerators for all SDLC activities, Glemser can implement and deploy a fully validated system in approximately 10 weeks
- xmLabeling will continue to be developed and maintained to ensure compliance with evolving regulatory standards
- Glemser is currently developing new labeling solutions
 - *SPL for Documentum Compliance Manager (DCM) - 1Q09*
 - *SPL for SharePoint – mid 2009*
- xmLabeling provides a structured content authoring platform to manage any type of submissible content in XML format, such as clinical study protocols and reports
- Glemser also performs SPL conversion services, called *SPL on Demand*
 - Utilizes secure portal
 - Provides full lifecycle management
 - Can be utilized as a temporary solution until production system is deployed

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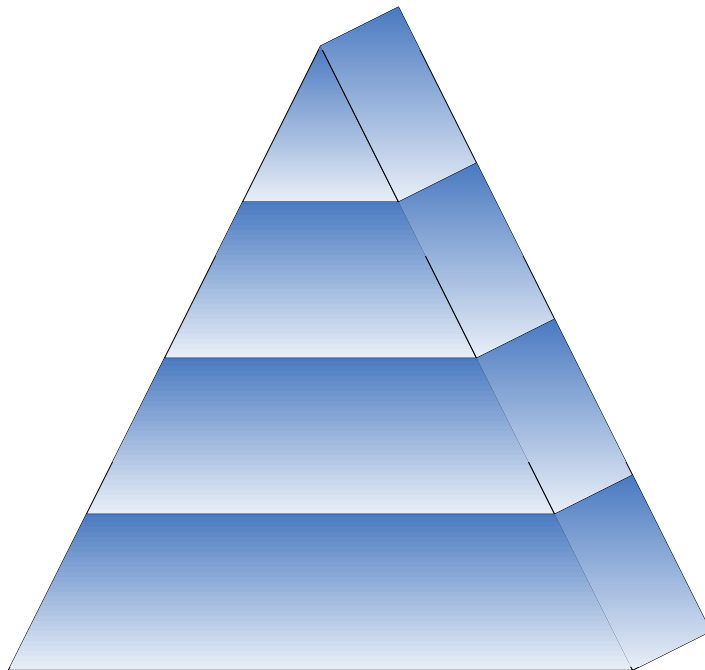
xmLabeling Key Design Principles

- Global Use and Scalability
- Agency Neutral XML Format
- Full Lifecycle Support
- User-Friendly XML Editor
- Robust Security Model
- Rapid Solution Deployment
- Efficient and Effective Validation



Key Design Principle – Global Use and Scalability (1 of 4)

xmLabeling has been architected to support a variety of global content management needs

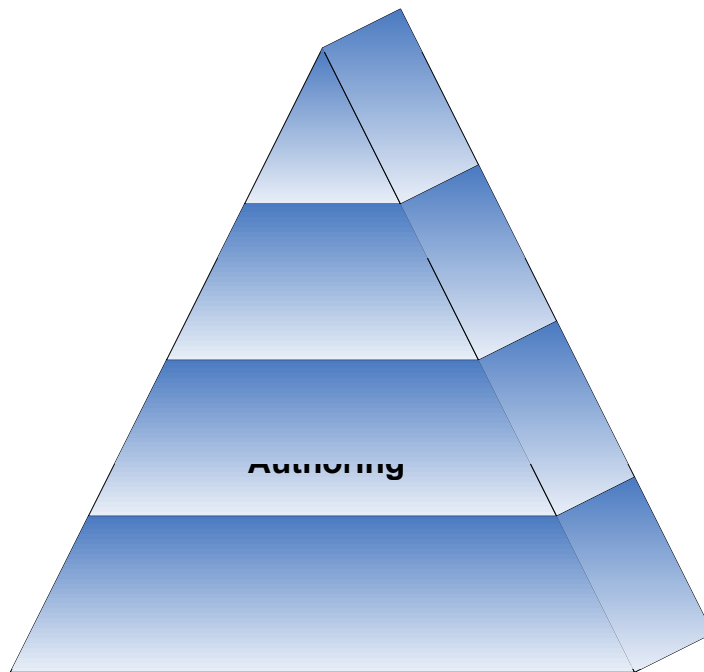


- Workflow
- Electronic Signatures
- Version Control
- Audit Trail
- Legal Hold
- Change Requests
- Periodic Review
- Effective Date Processing
- Notification
- Etc.



Key Design Principle – Global Use and Scalability (2 of 4)

xmLabeling has been architected to support a variety of global content management needs

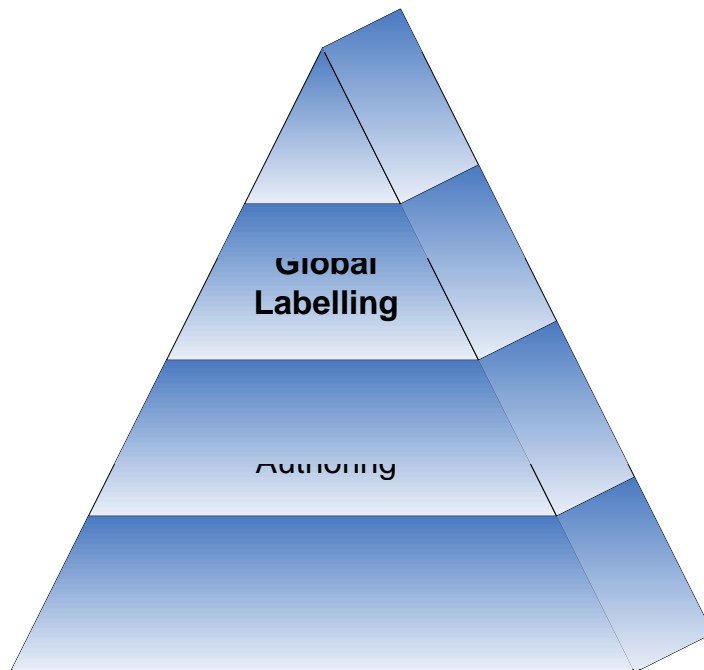


- XML Authoring
 - Xpress Author
 - Epic
 - Others
- Transformation Services
- Content Fragment Management
 - Assembly
 - Re-use
- Document Comparison
- Etc.



Key Design Principle – Global Use and Scalability (3 of 4)

xmLabeling has been architected to support a variety of global content management needs

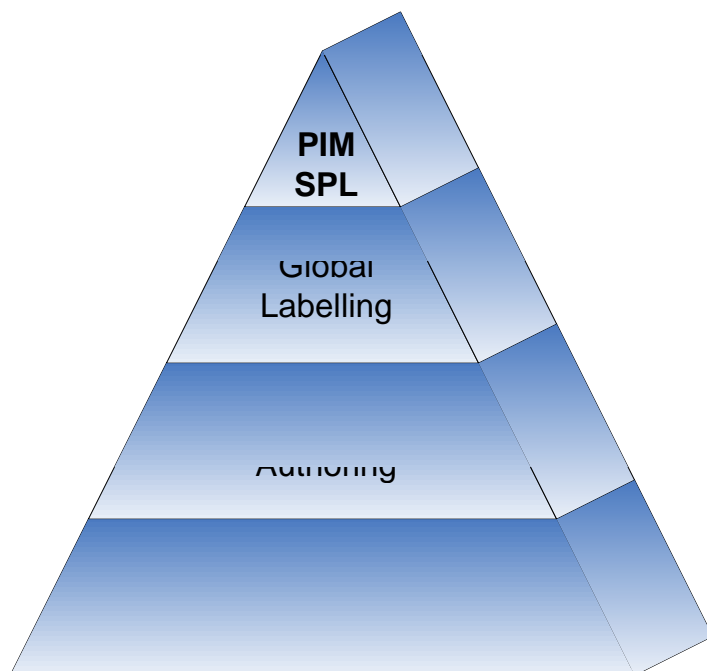


- Core Data Sheet Management
- Compliance Tracking
- Parallel Branch Versions
 - Variations
 - CBEs
 - Pre-Approvals
 - Post Approvals
- Translation Management
- Health Authority Interactions
- Etc.



Key Design Principle – Global Use and Scalability (4 of 4)

xmLabeling has been architected to support a variety of global content management needs



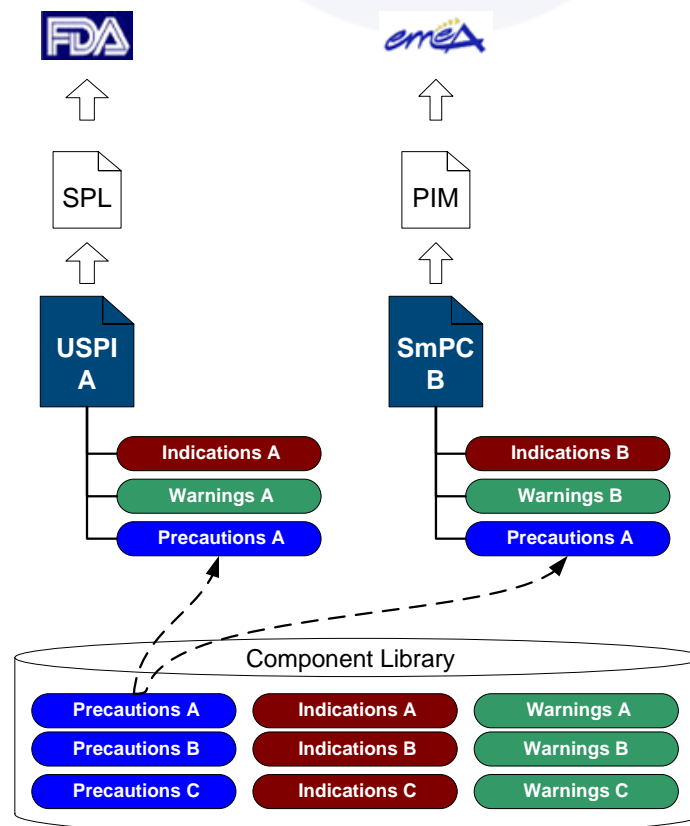
- SPL/PLR
 - Generate SPL
 - Generate PLR
 - Import SPL/PLR from DailyMed
 - Version Tracking
- PIM Output
 - Full
 - Delta
 - Multi-Lingual
 - Health Authority Commenting



Key Design Principle – Agency Neutral XML Format

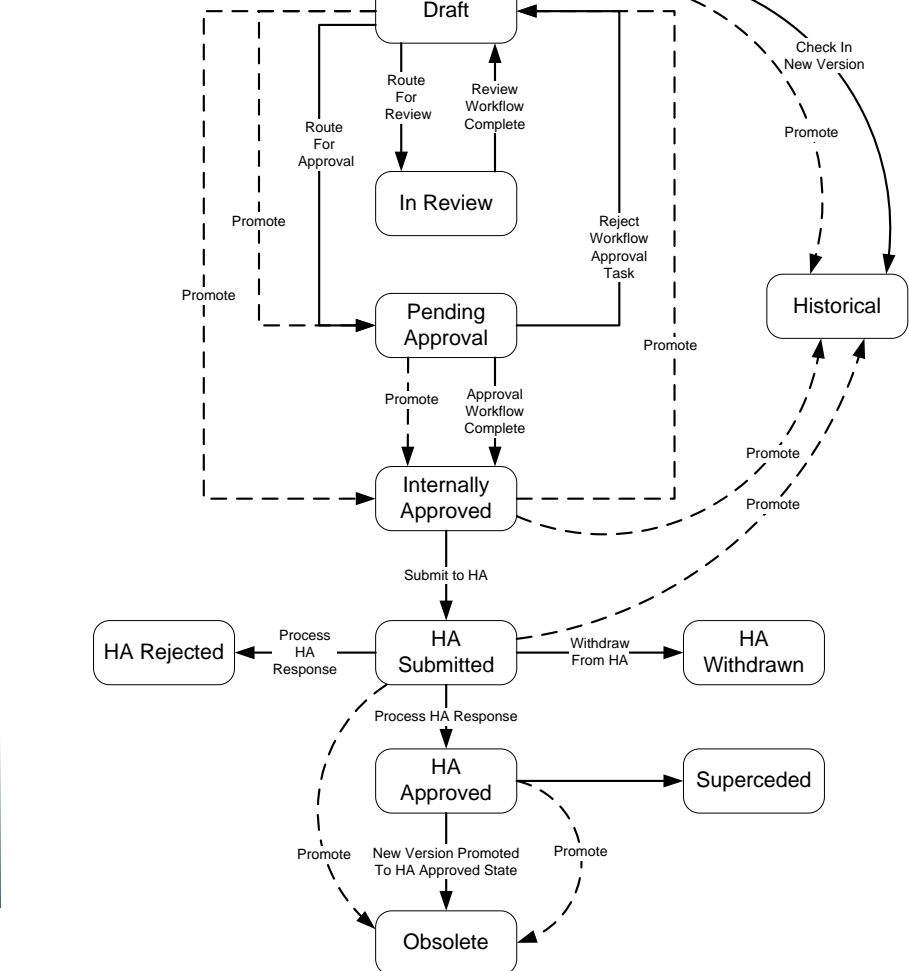
xmlLabeling manages labeling content in a generic, agency-neutral, author-friendly XML format

- Transforms neutral content to agency-specific formats, such as SPL and PIM, for submission to health authorities
- Improves content re-use by allowing common text to be included in both SPL and PIM submissions
- Reduces user training and support requirements because users do not need to learn multiple XML schemas
- Avoids content changes when the XML standards evolve
 - ◆ Enables seamless upgrade from SPL R3 to SPL R4



Key Design Principle - Full Lifecycle Support

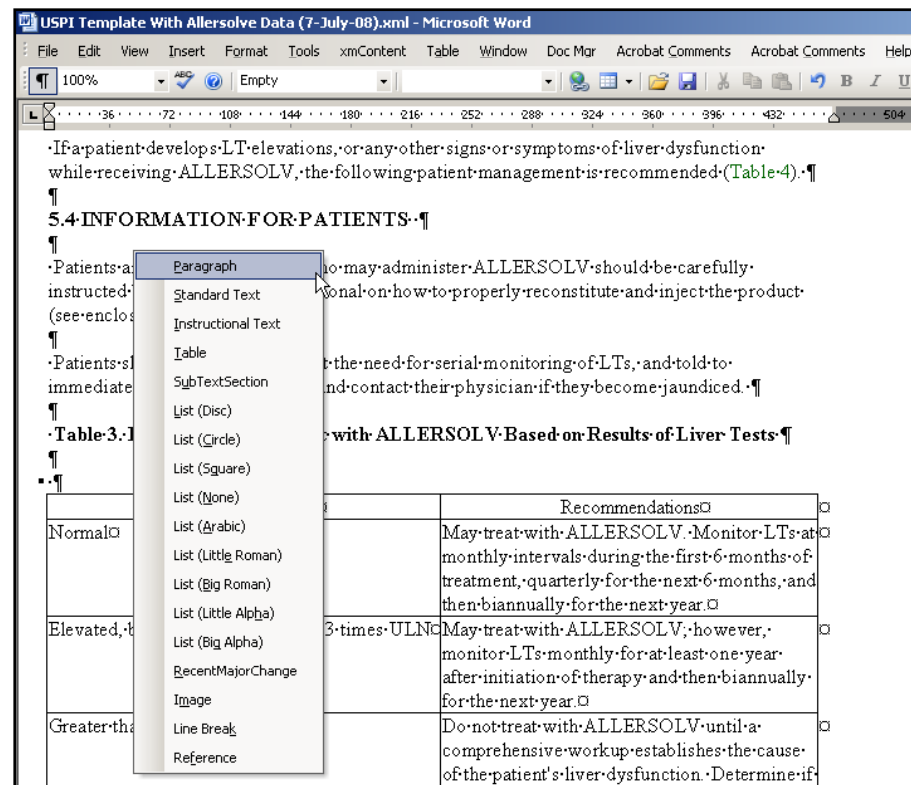
xmlLabeling includes complete support for the complex lifecycle of labeling documents both within your company and after submission to the regulator





Key Design Principle - User Friendly XML Editor

Authors typically don't like to author XML content at first. Utilize a MS Word-like editor, such as Quark's Xpress Author

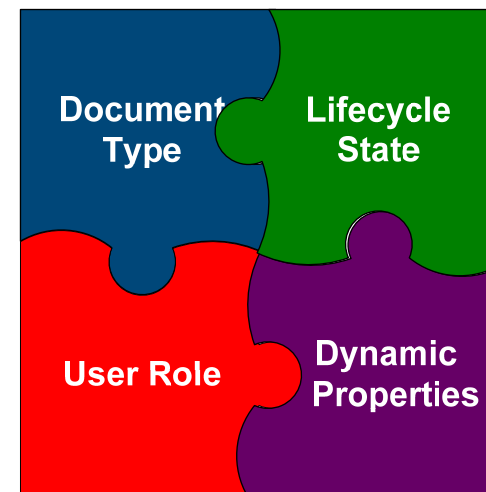




Key Design Principle - Robust Security Model

Access to documents and components should be managed through a dynamic security model based on multiple, configurable properties, ensuring only appropriate access is obtained

- Security based on:
 - ◆ Document type
 - ◆ Lifecycle state
 - ◆ User role
 - ◆ Country * (Property-based)
 - ◆ Product * (Property-based)





Key Design Principle – Rapid Solution Deployment

xmLabeling can be implemented and deployed in approximately 10 weeks using OTB functionality, best practice configurations, and pre-packaged implementation accelerators for all SDLC phases

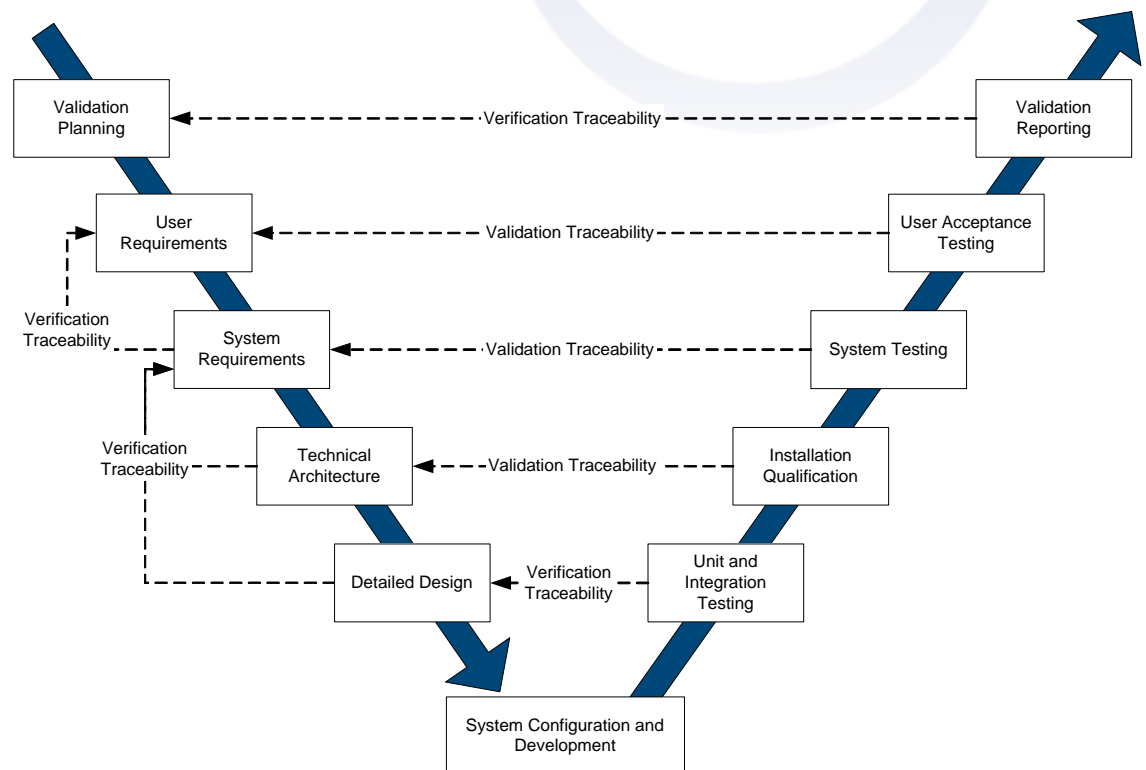


- Validation Plan
- Project Plan
- System Requirements Specification
- Configuration Requirements Specification
- Technical Architecture Specification
- Installation Qualification
- Unit, System and User Acceptance Test
 - Test Plans
 - Scripts
 - Reports
- Training Documentation



Key Design Principle – Efficient and Effective Validation

- Validation approach based
 - IEEE standards
 - GAMP guidelines
 - Glemser best practices
- Validation traceability is built into all project deliverables



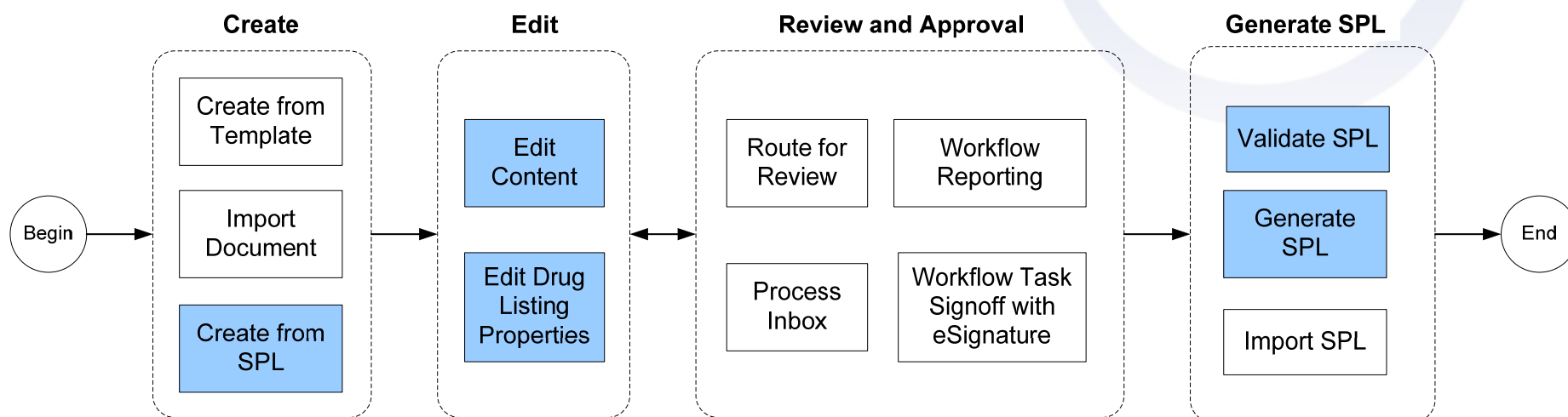


`<xmLabeling®/>` *Demonstration*

- Content of Labeling / Listing
- NDC Labeler Code Request
- Establishment Registration

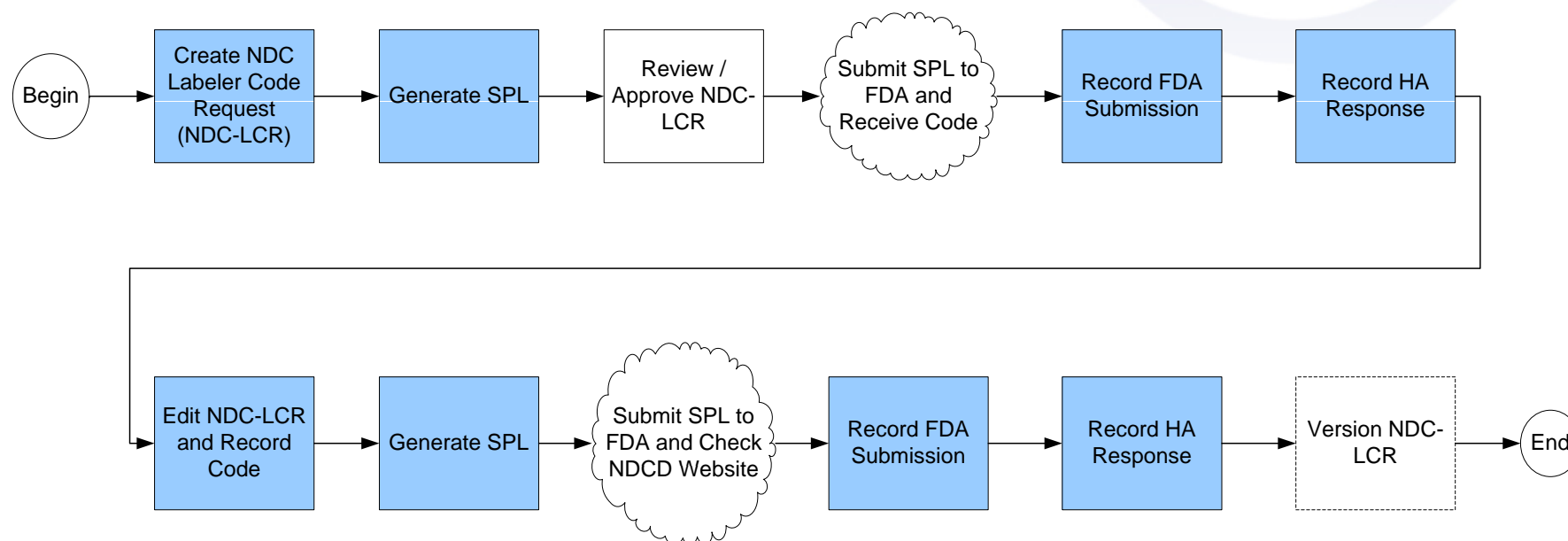


Content of Labeling / Drug Listing High Level Business Process





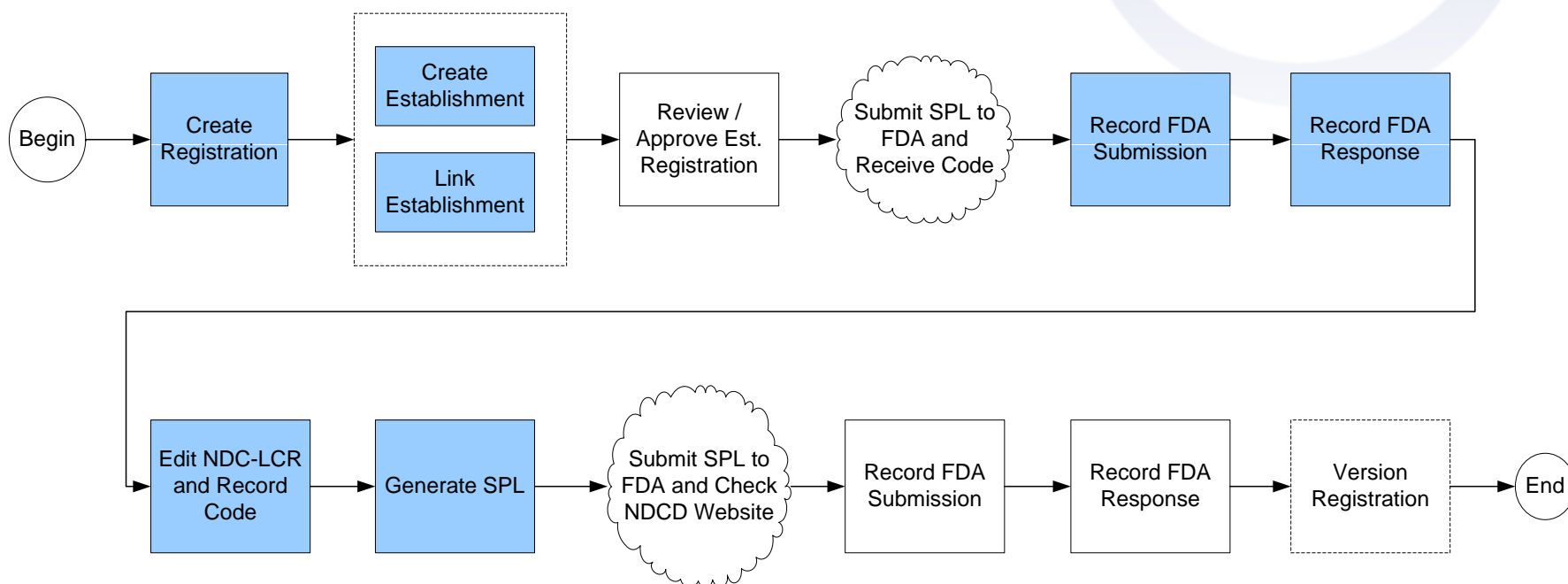
NDC Labeler Code Request High Level Business Process



NDCD = National Drug Code Directory



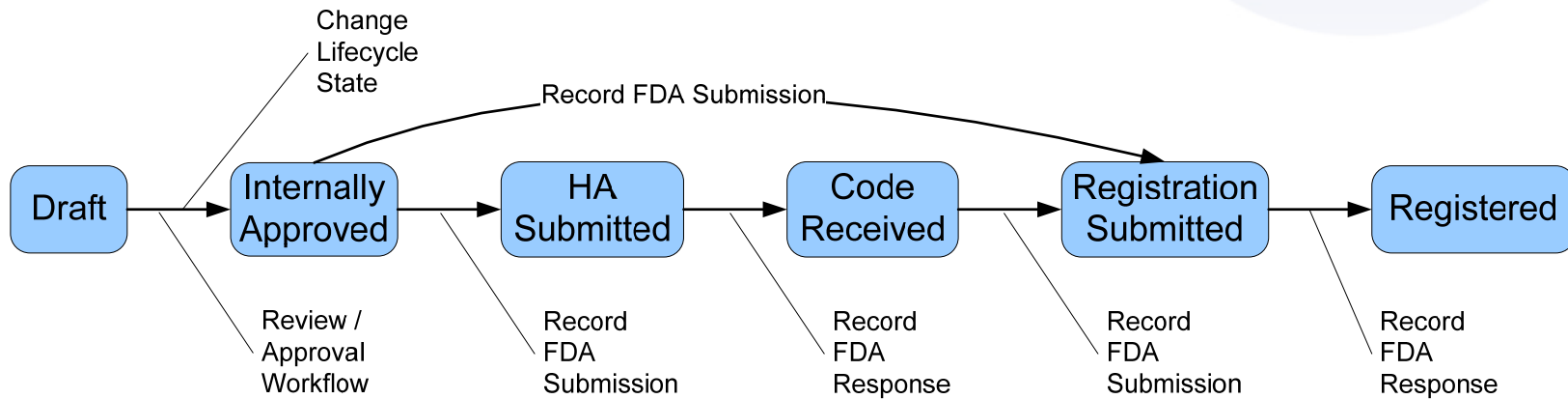
Establishment Registration High Level Business Process



NDCD = National Drug Code Directory



NDL-LCR and Registration Lifecycle States





Questions and Answers



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